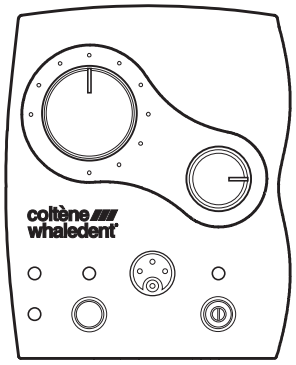

BioSonic® US100R

Ultrasonic Scaler System

EN Owner's Guide

DE Benutzerhandbuch

FR Guide d'utilisation

ES Guia de uso

IT Guida per l'utente

NL Gebruiksaanwijzing

SV Bruksanvisning

DA Brugerhåndbog

FI Käyttöohje

NO Brukerveiledning

PT Instruções de utilização

EL Οδηγίες Χρήσεως

CE 0344

coltène whaledent®

BioSonic® Ultrasonic Scaler

CAUTION: Federal law restricts this device to sale by or on the order of a dentist.

An essential part of your periodontal and prophylaxis therapy

Congratulations on your purchase of a Coltène/Whaledent BioSonic model US100R Ultrasonic Scaler — the finest, most efficient scaler in dentistry.

Developed specifically for dentistry, Coltène/Whaledent BioSonic model US100R Ultrasonic Scaler (hereinafter referred to in this manual as the "unit") is uniquely designed to save time and space, and increase safety in the dental treatment area.

What is scaling?

Scaling is the process by which calculus is removed from the tooth surface. This can be accomplished using either hand instruments (such as hand scalers or curettes) or ultrasonic scalers. When using ultrasonic scalers, high frequency waves generated within the ultrasonic handpiece cause the tip of the insert to vibrate at 25,000 or 30,000 cycles per second. This action can remove calculus from tooth surfaces more effectively and more rapidly than hand instruments.

Ultrasonic applications

- Routine debridement
- Periodontal therapy

I. Unpacking

A. Remove the unit from the shipping carton and inspect it for any damage which may have occurred during shipping.

The shipping carton should contain:

1 US100R Unit
1 Handpiece Assembly
1 Foot Switch Assembly
1 Water Line Assembly with Filter
1 Power Cord
1 Owner's Guide
1 Warranty Card
1 Quick Start-up Reference Guide
2 Spare Filters

B. Check the serial number on the underside of the unit against the number on the shipping carton. If these numbers are not the same, contact your dealer.

C. Complete the warranty card and mail to Coltène/Whaledent within 10 days of receipt.

D. Position the unit for easy access during patient treatment and also near a wall receptacle and cold water line. Make sure that the unit is placed on a solid surface, such as a counter top.

II. Set Up

A. Water (H_2O) line connectors

- Incoming cold water supply line pressure to the unit must be a minimum of 25 psi (172 kPa/1.724 bar) to a maximum of 50 psi (345 kPa/3.447 bar).
- The use of an in-line filter to be placed between the main shut-off valve and the unit is recommended. The main shut-off valve is a part of the plumbing in the operatory.
- Although the unit has a filter, it is not intended to replace a filter in the main line. The filter will capture smaller particles to further prevent handpiece clogging.
- The dental water line should be thoroughly flushed prior to connection to the unit.

B. Water supply line connection

- Insert water line tube into fitting located on the rear of the unit. Fitting will grip the tube before a complete seal is made. Make sure the tube is pushed all the way into the tube stop. Pull on the tube to insure it is secure. **(Fig. 1 & 2)**
- Check to ensure in-line filter is tightly attached to both sections of the tube.
- Connect other end of tube to office cold water supply line.
- Open the main shut-off valve.
- Inspect all connections to make certain there are no leaks.

C. Handpiece

- Push the connector on the handpiece assembly into the connector in the front of the unit. The connector will fit only in one way. **(Fig. 3)**
- Be sure the handpiece is securely connected.

D. Foot Switch Assembly

- Push the foot switch connector into the back of the unit. **(Fig. 4)**

E. Power cord/power connection

- Plug the detachable power cord into the back of the unit **(Fig. 5).**
- Insert the grounded plug supplied with the unit into a properly grounded electric receptacle, preferably "Hospital Grade."
- NOTE: If the grounded plug supplied with the unit does not fit the electric receptacle in your office, contact your dealer or the manufacturer for instructions. The unit is manufactured in two versions, one for use with 90–126 VAC, and one for use with 198–265 VAC. Make certain you are using the correct unit for the VAC supplied to your office. Use of the wrong mains voltage or use of an unauthorized voltage converter will void the unit's warranty.
- Check the LED above the ON/OFF push button switch. If it is illuminated (green), the unit is ON. If it is not illuminated, depress the switch button to turn the unit on. The unit is shipped with the switch in the OFF position.

F. Frequency Switch

- Move switch on the back of the unit to the correct frequency for the insert you will be using. The BioSonic US100R is preset at 30K. **(Fig. 6)**

III. Operating Instructions

A. Patient preparation and positioning

- Have the patient perform an antimicrobial pre-procedural mouthrinse to reduce bacterial contamination of the aerosol.
- Place the dental chair in a supine position for optimal access to both the maxillary and mandibular arches. This improves patient comfort and increases clinician visibility.
- Position the patient's head for optimum access to the quadrant and tooth surface being treated. Evacuate water and debris with a saliva ejector or high volume evacuator.

B. Ultrasonic scaling procedures

NOTE: Refer to section IV (Maintenance and Infection Control) of this Owner's Guide for general procedures to follow daily and between patients.

General operating procedures:

1. Be sure the main dental office water supply valve is open.
2. Turn the unit ON using the ON/OFF button. Verify that the green LED on the bottom right hand corner of the unit is lit.
3. Set the H_2O control knob clockwise to the fully open position.
4. Hold the handpiece (without an insert installed) over a sink or drain. Depress the foot control and flush the water line for at least 2 minutes.
5. Select the sterilized scaler insert.

6. Lubricate the O-ring with water before placing the insert into the handpiece. Depress the foot switch pedal while filling the handpiece with water and slowly turning the insert until it snaps into place. **(Fig. 7)**
7. Set the power and H_2O control knobs to your preferred operating positions. NOTE: Use the lowest effective power setting possible when scaling. (Scaler inserts should be sterilized before first use on each patient. See section IV, part A.)

C. "Turbo" feature

- The "Turbo" button on the bottom left corner of the unit may be depressed to switch to maximum power, without having to adjust the preferred power setting. When the "Turbo" mode is selected, a yellow LED above the button will be lit.
- It is not possible to adjust the power with the power knob as long as the "Turbo" is on.
- To turn the "Turbo" mode off, depress the button again. The yellow LED will not be lit.
- The "Turbo" feature is helpful to remove stubborn pieces of calculus, and should only be used as a temporary mode of operation.
- It may be necessary to adjust the H_2O knob with the unit in "Turbo" mode to assure adequate fluid delivery to the tip and the tooth.

D. Helpful hints

- **Use the lowest effective power setting possible when scaling.**
- If the handpiece becomes hot to the touch, there is either too little water, too much power or both. Adjust power and/or water settings accordingly.
- The rubber O-ring on the insert must be lubricated with water before placing it in the handpiece. Not lubricating the O-ring will make proper seating more difficult. Fully seat insert by pushing inward while twisting until seated. DO NOT FORCE. The handle on the insert should be flush against the handpiece. Alternatively, lubricating the O-ring with a small amount of petroleum jelly could prolong the life of the O-ring.
- Check and verify that fluid is reaching the working end of the insert tip by holding the handpiece over a sink or drain and activating the unit. Adjust the H_2O control knob to ensure adequate flow is achieved for the selected power setting. A fine mist should be spraying from the scaler insert tip **(Fig. 8)**.
- If water fails to flow properly, check supply line filter for clogging. Filters are disposable. Replace if necessary. Do not attempt to unclog used filters.
- To prevent accidental contact with the lips, tongue, and cheek, the scaler insert should be activated just before contacting the tooth, but after the insert has been placed in the patient's mouth.
- It is best to hold the handpiece in a pen grasp, using a very light touch when scaling both supra and subgingivally. Too much pressure of the tip against the tooth surface will decrease the effectiveness of the insert, as tip vibration is obstructed.
- Periodically check the scaler insert for wear.
- Develop an operating sequence in scaling to ensure thoroughness, and to minimize adjustments in patient and/or operator position.

E. Patient discomfort can be caused by:

- Excessive pressure. Apply the side of the scaler tip gently to tooth surface using very little pressure.
- Incorrect tip positioning. Avoid contact of the scaler insert tip and the tooth. Direct the tip away from root surfaces, and use side of scaler insert only.
- Not keeping the tip in motion on tooth. The tip should always be in motion during scaling. Use vertical, horizontal, or oblique overlapping strokes to increase scaling efficiency and decrease discomfort.
- If sensitivity persists, alternate treatment of sensitive areas and less sensitive areas and/or decrease power setting.

IV. Maintenance and Infection Control

A. Before each patient

1. Use a sterilized ultrasonic insert for each patient. (Scaler inserts should be sterilized before first use on each patient. Follow sterilization directions on scaler insert packaging.)
2. Clean and disinfect the surfaces of the cabinet, unit, power cord, and handpiece with Alpet D2 or BioSonic Wipeout. Apply barrier sleeves to the unit and the handpiece to reduce the risk of cross-contamination.
3. Flush the water supply lines as discussed previously in section II.
4. Place the sterilized scaler insert into the handpiece while maintaining proper asepsis techniques.

B. At the end of each day

1. Remove all ultrasonic inserts, clean and sterilize as applicable.
2. Clean and disinfect the unit and peripherals as done before each patient. Clean components by wiping with a soft cloth moistened with a commercially available mineral deposit remover followed by an intermediate level disinfectant.

CAUTION: Do not use petroleum based solvents, iodophors or phenolic based products. (Iodophors and phenolics can stain the surface of the unit.) Clean up all liquid spills immediately.

3. Flush all water lines thoroughly.
4. Turn the unit OFF.
5. Close the main shut-off valve from the dental water supply.

C. Inspecting the power cord, water lines, filter and handpiece

- Periodically check and inspect the power cord, water lines, filter and handpiece for damage, wear or clogging.
- Check connectors at both ends of the cord to make sure they are fully seated.

D. Inspecting the scaler insert O-ring

- Inspect the rubber O-ring for wear and/or damage. O-rings will wear over time due to repeated sterilization. When the O-ring is worn and/or damaged, leakage will occur between the handpiece and the scaler insert.
- Roll the worn or damaged O-ring over the laminate stack off the scaler insert, and roll a new O-ring onto the scaler insert until seated in the groove on the colored plastic grip.

E. Changing the fuse

WARNING: Replace fuses as marked. Replace the fuse with the exact fuse type and rating to avoid risk of fire.

For 100/115 VAC 5 x 20 mm Slo-Blo 1.6 Amp, 250V
P/N: 03821-20
For 230/240 VAC 5 x 20 mm T-Type 0.8 Amp, 250V
P/N: 03321-16

- The fuse compartment is located immediately below the power cord receptacle on the unit. Open the compartment with a small screw driver **(Fig. 9)**.
- Inspect the fuse **(Fig.10)**. A good fuse is shown on the left of **Fig. 10**, a blown fuse is shown on the right.
- Replace the fuse when necessary, and close compartment until a click is heard.

V. Environmental/Storage Conditions

Environmental Conditions

- Intended for indoor use
- Maximum altitude : 2000m (6600 ft.)
- Temperature range: 5°C (41°F) – 40°C (104°F)
- Relative humidity: 50% @ 40°C (104°F) – 80% up to 31°C (88°F)

Storage Conditions

The unit must be stored and transported within the following conditions:

- Temperature range: -40°C (-40°F) – 70°C (158°F)
- Relative humidity: (non-condensing) 10% – 100%
- Atmospheric pressure: 500hPa – 1060hPa

VI. Warnings

- Use cold water only.
- Do not use the ultrasonic scaler without water.
- Do not touch the metal working tip of an activated Ultrasonic Scaler with bare hands, as it will cause minor burns.
- Do not use ultrasonics for dental procedures involving the condensation of amalgam.
- To assure optimum performance use only inserts manufactured by Coltène/Whaledent Inc.
- Do not restrict air flow. Provide adequate ventilation.
- Do not subject unit to shock or impact.
- Do not immerse unit in water.
- This product is intended for use by trained healthcare professionals only.
- Use this product in accordance with the instructions in the Owner's Guide.
- Unspecified or improper use of this product may impair safety protection.
- Do not place the unit on or next to a radiator or other heat source. Excessive heat may damage the unit components. Place the unit in well ventilated areas.
- Flush water supply to this device regularly.
- Close the main shut-off valve to the unit before leaving each day.
- Do not use this device for any type of dental surgery.
- Ground fault interrupt electrical outlets are recommended for use with any electromechanical devices that are used with or near water.
- Equipment not suitable for use in the presence of flammable mixtures.
- Handpiece cannot be sterilized. Use Alpet D2 or BioSonic Wipeout to disinfect handpiece.

VII. Precautions for Ultrasonic Prophylaxis Procedures

- Ultrasonic inserts "wear out" with use. Inserts that have 2 mm of wear lose about 50% of their scaling efficiency.
- If excessive wear is evident, or the insert has been bent, discard the insert immediately. It may break during use.
- Use retraction to protect the tongue, cheek and lips when the scaler is in use to avoid contact between the two.

VIII. Order Information

Units:

Catalog No.	Voltage	Frequency	Power
US100R100	100V	50/60 Hz	100W max
US100R115M	115V	50/60 Hz	100W max
US100R115T	115V	50/60 Hz	100W max
US100R230CE	230V	50/60 Hz	100W max
US100R230UK	230V	50/60 Hz	100W max
US100R240	240V	50/60 Hz	100W max

Inserts: Catalog No.	Frequency 25 kHz Description	Qty
US1025K	#10 Universal	1
USG1025K	#10 SuperSoft™	1
US1025KOM	#10 OptiMist™	1
US1025KSP	#10 Universal Slim	1
USG1025KSP	#10 Slim SuperSoft	1
US1025KOS	#10 Slim OptiMist	1
USG1025KOS	#10 Slim SuperSoft (Optimist)	1
US100025K	#1000 Universal Triple Bend	1

Inserts:	Frequency 30 kHz	Qty
US1030K	#10 Universal	1
USG1030K	#10 SuperSoft	1
US1030KOM	#10 OptiMist	1
US1030KSP	#10 Universal Slim	1
USG1030KSP	#10 Slim SuperSoft	1
US1030KOS	#10 Slim OptiMist	1
USG1030KOS	#10 Slim SuperSoft (Optimist)	1
US100030K	#1000 Universal Triple Bend	1
US10OR (OR-alpha)	Replacement O-Ring Gaskets	1
US100RXF	Water Filter Replacement Kit	1

IX. Troubleshooting

Generally, check all lines and connections to and from the unit, a loose plug or connection will often create problems. Check the settings on the unit's knobs. Although service and repair of the BioSonic US100R ultrasonic scaler should be performed by authorized personnel, the following are some basic trouble shooting procedures that will help avoid unnecessary service calls.

A. Unit will not operate

1. Check the ON/OFF switch making sure it is in the ON position, and that the detachable power cord is fully seated in the receptacle on back of unit (ON/OFF indicator light should be on).
2. Check that the unit's electrical plug is fully seated in an appropriate AC receptacle, and that the receptacle is active.

B. No water at insert

1. Assure that the H_2O control is properly adjusted. A fine mist or rapid drip of water should be observed at the tip of the insert.
2. Check that the main shut-off valve is open.

3. Check the disposable in-line water filter for possible clogging.
4. Check the recommended customer supplied in-line water filter for possible clogging.
5. Make sure that the water lines are not kinked.
6. Make sure that the water knob is turned to the "open" position (clockwise).

C. Unit sprays water, but the same insert does not vibrate

- Try a different insert. Sometimes a worn out and/or damaged insert is not detectable to the naked eye.
- Check indicator light to see if unit is set to the same frequency as the insert. If not, move switch on the back of the unit to the correct frequency.

X. Specifications

A. Unit

Catalog Number	Voltage	Frequency	Power
US100R100	100V	50/60 Hz	100W max
US100R115M	115V	50/60 Hz	100W max
US100R115T	115V	50/60 Hz	100W max
US100R230CE	230V	50/60 Hz	100W max
US100R230UK	230V	50/60 Hz	100W max
US100R240	240V	50/60 Hz	100W max

Operating Frequency	25/30 kHz
Power Consumption	40-70 W
Overall Dimensions	5.5 x 9 x 6 inches (13.97 x 22.86 x 15.24 cm)
Weight	10lbs (4.54kg)
Fuse Type	5 x 20 mm, Slo-Blo Fuses
	100–115V units 1.6 Amp, 250 V T-Type
	230–240V units 0.8 Amp, 250 V T-Type

B. Insert

Catalog No.	Frequency	Catalog No.	Frequency
US1025K	25 kHz	US1025KOS	25 kHz
US1030K	30 kHz	US1030KOS	30 kHz
US1025KSP	25 kHz	USG1025K	25 kHz
US1030KSP	30 kHz	USG1030K	30 kHz
US100025K	25 kHz	USG1025KSP	25 kHz
US100030K	30 kHz	USG1030KSP	30 kHz
US1025KOM	25 kHz	USG1025KOS	25 kHz
US1030KOM	30 kHz	USG1030KOS	30 kHz

IEC Symbol
Publication: 417-5019
Protective earth (ground)

IEC Symbol
Publication: 348
Attention: Consult accompanying documents

IEC Symbol
Publication: 878-02-03
Type BF Equipment

IEC Symbol
Publication: 878-01-71
Foot Switch

ISO Symbol
Publication: 7000-0536
Water Connector

IEC Symbol
Publication: 417-5016
Fuse

Complies with MDD/93/42/EEC

XI. Classifications

Protection against electrical shock: Class 1
Protection against ingress of water: Ordinary (IPX0)
Mode of operation: Continuous

Clean and disinfect the surfaces of the cabinet, unit, power cord, and handpiece with Alpet D2 or BioSonic Wipeout.
Equipment not suitable for use in the presence of flammable mixtures .

XII. Disposal of unit / waste products

In accordance with local and state laws.

XIII. Limited Warranty

Our products are carefully manufactured to meet stringent quality assurance requirements. Our products are manufactured from new parts or new and serviceable used parts. Regardless, our warranty terms apply. This product has been developed specifically for use in dentistry and is intended to be operated only by qualified dental professionals in accordance with the instructions contained in this guide. However, notwithstanding anything contained herein to the contrary, the user shall at all times be solely responsible for determining the suitability of the product for the intended purpose and the method of its use. Any guidance on application technology offered by or on behalf of the manufacturer, whether written, verbal or by demonstration, shall not relieve the dental professional of his/her obligation to control the product and to make all professional judgments regarding its use.

Our products are warranted in accordance with the terms of a written Certificate of Limited Warranty accompanying each product. Except for the warranties specifically set forth in the Certificate of Limited Warranty, Coltène/Whaledent Inc. provides no warranties or guarantees of any kind covering the product, expressed or implied, including, without limitation, any warranties as to merchantability or fitness for a particular purpose. **The purchaser/user is referred to the Certificate of Limited Warranty for all of the terms, conditions and limitations of the warranty covering this product.** This Section of the user manual is not intended to in any way modify or add to the warranty provided in the Certificate of Limited Warranty.

Any claim for damage or breakage to the product in transit should be made to the carrier promptly upon discovery. C/W does not warrant the product against shipping damage.

XIV. EMC Information, Warnings and Considerations:

1. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instruction manual, may cause interference to radio communications. Operation of this equipment in a manner inconsistent with this manual is likely to cause interference in which case the user, at his own expense, will be required to take whatever measures may be required to correct the interference.
2. Persons fitted with cardiac pacemakers have been cautioned that some types of electronic equipment might interfere with the operation of a pacemaker. Although no instance of pacemaker interference relating to a BioSonic Ultrasonic Scaler has ever been reported to Coltène/Whaledent Inc., we recommend that the handpiece and cables be kept at least 6 to 9 inches (15 to 23 cm) away from any pacemaker and pacemaker leads during use. If use of this product is in question, consult patient's cardiologist.
3. Use of US100R cables and accessories, other than those provided by Coltène/Whaledent, may result in increased emissions or decreased immunity.
4. Listed cables:
    a. Handle & Cord Assembly – Coltene Part # 28223
    b. Footswitch & Cord Assembly – Coltene Part # 28225
5. Electromagnetic Compatibility:
   The following are guidance and manufacturer's declarations regarding electromagnetic compatibility for the BioSonic® US100R.

5.1 EN/IEC 60601-1-2 Table 1

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The BioSonic® US100R is intended for use in the electromagnetic environment specified below. The customer or the end user of the BioSonic® US100R should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11:2004	Group 1	The BioSonic® US100R uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11:2004	Class B	The BioSonic® US100R unit is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes, provided the following warning is heeded: **Warning:** This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the BioSonic® US100R unit or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

5.2 EN/IEC 60601-1-2 Table 2

	Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
	The BioSonic® US100R unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the BioSonic® US100R unit should assure it is used only in such an environment.			
	Immunity Test	IEC60601 test level	Compliance Level	Intended Electromagnetic Environment
	Electromagnetic discharge (ESD) IEC 61000-4-2	+- 6kV contact +- 8kV air	+- 6kV contact +- 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	Electrical fast transient/burst IEC 61000-4-4	+-2kV for power supply lines +-1kV for input/output lines	+-2kV for power supply lines +-1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
	Surge IEC 61000-4-5	+-1kV differential mode (line-line) +-2kV common mode (line-earth)	+-1kV differential mode (line-line) +-2kV common mode (line-earth)	Mains power quality should be that of a typical commercial or hospital environment.
	Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BioSonic® US100R unit requires continued operation during power mains interruptions, it is recommended that the BioSonic® US100R unit be powered from an uninterruptible power supply with sufficient capacity to run the unit for the maximum required time of interruption.
	Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
	Note UT is the a.c. mains voltage prior to application of the test level.			

5.3 EN/IEC 60601-1-2:2007 Sub-clause 5.2.2.2 Table 4:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The BioSonic® US100R unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the BioSonic® US100R unit should assure it is used in such an environment.			
Immunity Test	IEC60601 test level	Compliance Level	Intended Electromagnetic Environment
			Portable and mobile RF communications equipment should be used no closer to any part of the BioSonic® US100R unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms 150kHz to 80MHz	**Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m 80MHz to 2.5GHz	$d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended minimum separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from objects, structures and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BioSonic® US100R unit is used exceeds the applicable RF compliance level above, the BioSonic® US100R unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BioSonic® US100R unit. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

5.4 EN/IEC 60601-1-2:2007 Sub-clause 5.2.2.2 Table 6:

Recommended separation distances between portable and mobile RF communications equipment and the BioSonic® US100R unit.			
The BioSonic® US100R unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Product Name/Model unit can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the BioSonic® US100R unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter in watts (W)	Separation distance according to frequency of transmitter in meters (m)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	.12	.12	.23
0.1	.38	.38	.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			